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Group Art Unit: 1618

Attorney  
Docket: 26883

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Docket: 26883

## INFORMATION DISCLOSURE STATEMENT

Enclosed is a PTO Form 1449 which lists citations which may be material to the patentability and examination of the above identified application. Also enclosed are copies of the references cited. These are submitted in compliance with the duty of disclosure defined in 37 CFR 1.56. The Examiner is requested to make these citations of official record in this application.

This Supplemental Information Disclosure Statement is being filed subsequent to an Office Action being mailed and a late fee of \$180 is due. Please charge my Deposit Account 50-1407 for this fee, as well as any additional fees due.

This Information Disclosure Statement under 37 CFR 1.56 is not to be construed as a representation that a search has been made, that additional matter which is material to the examination of this application does not exist, or that any or more of these citations constitutes prior art.

09/08/2006 MBERHE 00000008 501407 10671538  
Respectfully submitted,  
01 FC:1006 180.00 DA -  
*Martin D. Moynihan*  
Martin D. Moynihan  
Registration No. 40,338

Dated: August 16, 2006



PTO/SB/08a (08-03)

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|                                                                                                                                               |   |    |   | Application Number       | 10/671,538            |
|                                                                                                                                               |   |    |   | Filing Date              | September 29, 2003    |
|                                                                                                                                               |   |    |   | First Named Inventor     | Bernard S.GREEN et al |
|                                                                                                                                               |   |    |   | Art Unit                 | 1618                  |
|                                                                                                                                               |   |    |   | Examiner Name            | ROGERS, JAMES WILLIAM |
| Sheet                                                                                                                                         | 1 | of | 3 | Attorney Docket Number   | 26883                 |

**U.S. PATENT DOCUMENTS**

| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | Document Number                          | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|-----------------------|--------------------------|------------------------------------------|--------------------------------|----------------------------------------------------|---------------------------------------------------------------------------------|
|                       |                          | Number-Kind Code <sup>2</sup> (if known) |                                |                                                    |                                                                                 |
|                       | 1                        | US-5,858,296                             | 01-12-1999                     | Domb                                               |                                                                                 |
|                       | 2                        | US-4,127,730                             | 11-28-1978                     | Wulff et al.                                       |                                                                                 |
|                       | 3                        | US-5,110,833                             | 05-5-1992                      | Mosbach                                            |                                                                                 |
|                       | 4                        | US-5,587,273                             | 12-24-1996                     | Yan et al.                                         |                                                                                 |
|                       | 5                        | US-5,589,358                             | 12-31-1996                     | Dawson                                             |                                                                                 |
|                       | 6                        | US-5,630,978                             | 05-20-1997                     | Domb                                               |                                                                                 |
|                       | 7                        | US-5,631,138                             | 05-20-1997                     | Kano et al.                                        |                                                                                 |
|                       | 8                        | US-5,872,198                             | 02-16-1999                     | Mosbach et al.                                     |                                                                                 |
|                       | 9                        | US-5,945,411                             | 08-31-1999                     | Larson et al.                                      |                                                                                 |
|                       | 10                       | US-5,976,811                             | 02-2-1999                      | Müllner et al.                                     |                                                                                 |
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**FOREIGN PATENT DOCUMENTS**

| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | Foreign Patent Documents                                                          | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures Appear | T<br>6 |
|-----------------------|--------------------------|-----------------------------------------------------------------------------------|--------------------------------|----------------------------------------------------|---------------------------------------------------------------------------------|--------|
|                       |                          | Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known) |                                |                                                    |                                                                                 |        |
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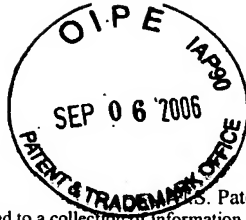
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| Examiner<br>Signature | Date<br>Considered |
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<sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br><i>(use as many sheets as necessary)</i> |                       |                                                                                                                                                                                                                                                                                         | Application Number   | 10/671,538             |                |
|                                                                                                          |                       |                                                                                                                                                                                                                                                                                         | Filing Date          | September 29, 2003     |                |
|                                                                                                          |                       |                                                                                                                                                                                                                                                                                         | First Named Inventor | Bernard S.GREEN et al  |                |
|                                                                                                          |                       |                                                                                                                                                                                                                                                                                         | Group Art Unit       | 1618                   |                |
|                                                                                                          |                       |                                                                                                                                                                                                                                                                                         | Examiner Name        | ROGERS, JAMES WILLIAM  |                |
| Sheet                                                                                                    | 2                     | Of                                                                                                                                                                                                                                                                                      | 3                    | Attorney Docket Number | 26883          |
| OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS                                                        |                       |                                                                                                                                                                                                                                                                                         |                      |                        |                |
| Examiner Initials                                                                                        | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.                           |                      |                        | T <sup>2</sup> |
|                                                                                                          | 11                    | Haupt et al. "Plastic Antibodies: Development and Applications", TIBTECH, 16: 468-475, 1998.                                                                                                                                                                                            |                      |                        |                |
|                                                                                                          | 12                    | Mayes et al. "Molecularly Imprinted Polymers: Useful Materials for Analytical Chemistry?", Trends in Analytical Chemistry, 16(6): 321-332, 1997.                                                                                                                                        |                      |                        |                |
|                                                                                                          | 13                    | Vlatakis et al. "Drug Assay Using Antibody Mimics Made by Molecular Imprinting", Nature, 361: 645-647, 1993.                                                                                                                                                                            |                      |                        |                |
|                                                                                                          | 14                    | Kauer et al. "Composition and Concentration of Bile Acid Reflux Into the Esophagus of Patients With Gastroesophageal Reflux Disease", Surgery, 122: 874-881, 1997.                                                                                                                      |                      |                        |                |
|                                                                                                          | 15                    | Ochsenkühn et al. "Colonic Mucosal Proliferation Is Related to Serum Deoxycholic Acid Levels", Cancer, 85: 1664-1669, 1999.                                                                                                                                                             |                      |                        |                |
|                                                                                                          | 16                    | Shirvani et al. "Cyclooxygenase 2 Expression in Barrett's Esophagus and Adenocarcinoma: Ex Vivo Induction by Bile Salts and Acid Exposure", Gastroenterology, 118: 487-496, 2000.                                                                                                       |                      |                        |                |
|                                                                                                          | 17                    | Theisen et al. "Suppression of Gastric Acid Secretion in Patients With Gastroesophageal Reflux Disease Results in Gastric Bacterial Acids", Journal of Gastrointestinal Surgery, 4: 50-54, 2000.                                                                                        |                      |                        |                |
|                                                                                                          | 18                    | Kamano et al. "Ratio of Primary and Secondary Bile Acids in Feces: Possible Marker for Colorectal Cancer?", Dis Colon Rectum, 42(5): 668-672, 1999. Abstract.                                                                                                                           |                      |                        |                |
|                                                                                                          | 19                    | Nehra et al. "Toxic Bile Acids in Gastro-Oesophageal Reflux Disease: Influence of Gastric Acidity", GUT, 44(5): 598-602, 1999. Abstract.                                                                                                                                                |                      |                        |                |
|                                                                                                          | 20                    | Shindo et al. "Omeprazole Induces Altered Bile Acid Metabolism", GUT, 42: 266-271, 1998. Abstract.                                                                                                                                                                                      |                      |                        |                |
|                                                                                                          | 21                    | Zhang et al. "Dihydroxy Bile Acids Activate the Transcription of Cyclooxygenase-2", The Journal of Biological Chemistry, 273(4): 2424-2428, 1998.                                                                                                                                       |                      |                        |                |
|                                                                                                          | 22                    | Whitcombe et al. "A New Method for the Introduction of Recognition Site Functionality Into Polymers Prepared by Molecular Imprinting: Synthesis and Characterization of Polymeric Receptors for Cholesterol", Journal of the American Chemical Society, 117: 7105-7111, 1995. Abstract. |                      |                        |                |
|                                                                                                          | 23                    | Bayerdorffer et al. "Unconjugated Secondary Bile Acids in the Serum of Patients With Colorectal Adenomas", GUT, 36(2): 268-273, 1995. Abstract.                                                                                                                                         |                      |                        |                |
|                                                                                                          | 24                    | Berr et al. "Disorders of Bile Acid Metabolism in Cholesterol Gallstone Disease", Journal of Clinical Investigation, 90(3): 859-868, 1992.                                                                                                                                              |                      |                        |                |
|                                                                                                          | 25                    | Bernstein et al. "A Bile Acid-Induced Apoptosis Assay for Colon Cancer Risk and Associated Quality Control Studies", Cancer Research, 59(10): 2353-2357, 1999.                                                                                                                          |                      |                        |                |
|                                                                                                          | 26                    | Fuhrman et al. "Increased Uptake of LDL by Oxidized Macrophages Is the Result of An Initial Enhanced LDL Receptor Activity and of A Further Progressive Oxidation of LDL", Free Radic Biol Med, 23(1): 34-46, 1997. Abstract.                                                           |                      |                        |                |
| Signature                                                                                                |                       |                                                                                                                                                                                                                                                                                         | Considered           |                        |                |

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|                                                                                                                                               |    | Group Art Unit                                                                                                                                                                                                                                                                                     | 1618                  |                        |            |
|                                                                                                                                               |    | Examiner Name                                                                                                                                                                                                                                                                                      | ROGERS, JAMES WILLIAM |                        |            |
| Sheet                                                                                                                                         | 3  | Of                                                                                                                                                                                                                                                                                                 | 3                     | Attorney Docket Number | 26883      |
| <b>OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS</b>                                                                                      |    |                                                                                                                                                                                                                                                                                                    |                       |                        |            |
|                                                                                                                                               | 27 | Ljubuncic et al. "Effect of Deoxycholic Acid and Ursodeoxycholic Acid on Lipid Peroxidation in Cultured Macrophages", GUT, 39(3): 475-478, 1996. Abstract.                                                                                                                                         |                       |                        |            |
|                                                                                                                                               | 28 | Low-Beer et al. "Colonic Bacterial Activity, Biliary Cholesterol Saturation, and Pathogenesis of Gallstones", Lancet, 2(8099): 1063-1065, 1978. Abstract.                                                                                                                                          |                       |                        |            |
|                                                                                                                                               | 29 | Peiffer et al. "Differential Effects of Deoxycholic Acid on Proliferation of Neoplastic and Differentiation Colonocytes In Vitro", Digestive Diseases and Sciences, 42(11): 2234-2240, 1997. Abstract.                                                                                             |                       |                        |            |
|                                                                                                                                               | 30 | Shoda et al. "Increase of Deoxycholate in Supersaturated Bile of Patients With Cholesterol Gallstone Disease and Its Correlation With De Novo Syntheses of Cholesterol and Bile Acids in Liver, Gallbladder Emptying, and Small Intestinal Transit", Hepatology, 21(5): 1291-1302, 1995. Abstract. |                       |                        |            |
|                                                                                                                                               | 31 | Fini et al. "Spectrophotometric Determination of Bile Acids. An Evaluation", Collection of the Czechoslovakian Chemical Communications, 58(1): 53-61, 1993. Abstract.                                                                                                                              |                       |                        |            |
|                                                                                                                                               | 32 | Wulff "Molecular Imprinting in Cross-Linked Materials With the Aid of Molecular Templates - A Way Towards Artificial Antibodies", Angewandte Chemie, International Edition, 34: 1812-1832, 1995. Abstract.                                                                                         |                       |                        |            |
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